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U.S. Food and Drug Administration
Rm 1061
5630 Fishers Lane
Rockville, MD 20852

In re Docket No. 00N-1351

Submission on Behalf The Fresh Juice Company

TO WHOM IT MAY CONCERN:

These remarks are submitted on behalf of The Fresh Juice Company. They make fresh citrus juice along with a number of other products. The Fresh Juice Company's fresh citrus juice is distributed nationally. Since 1995, the company's fresh juice has been made under a program developed by the State of Florida which ensures supervision of the production of a pathogen-free citrus juice by assessment and control of critical points in its manufacture.

Statement

The company believes that, for citrus juice, the unqualified term "fresh" should be limited to juice that has undergone no post-extraction processing.

The Special Case of Citrus

There are three reasons why fresh citrus juice is a special case. First, there are labeling rules that are unique to fresh citrus juice that require that citrus juice that is labeled as "fresh" and which does not carry a warning label, must be able to demonstrate a 5-log microbial pathogen reduction without the use of pasteurization.

Recently, FDA promulgated rules governing the labeling of fruit juices that are directly applicable to the labeling discussions being held here today. 63 Fed. Reg. 37,030 (July 8, 1998). Those rules effectively require that fruit juices other than citrus be labeled with a warning statement unless they are pasteurized. There is an alternative for citrus — if a manufacturer can demonstrate a 5-log reduction in pertinent pathogenic micro-organisms, the juice can be "fresh;" a warning label is not required. While the "5-log" exception applies to all fruit juice, the company's understanding is that, to date, citrus juice is the only juice for which it has been demonstrated that these requirements can be met without any post-extraction treatments or processing. (The company hereby incorporates these regulations and the relevant docket by reference.) Thus, fresh citrus juice is unique under existing food labeling regulations governing warning statements for unpasteurized fruit juice.

Second, as a result of compliance with the foregoing regulations, FDA has proposed that fruit juice will soon be required to be in compliance with a proposed national HACCP program for fruit juice products. 63 Fed. Reg. 24,254 (May 1, 1998). (This proposal and the accompanying docket are incorporated herein by reference.) It is likely that this HACCP program will be applied to fresh (or unpasteurized) citrus juice soon, as such a program has specifically been recommended at a recent meeting of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (December 8-10, 1999). At that meeting, extensive discussion and debate was held on the methods needed to ensure high quality safe fresh citrus juice. See Transcript Attached at Tab 1. The focus of the discussion was on the unique, impermeable peel of the healthy citrus fruit. The panel concluded that fresh citrus juice can be made safely without any post-extraction treatments. This issue is relevant here today because one reason for the meeting in Chicago is to decide whether the meaning of the word "fresh" should be adjusted by regulations, to deal with the realities of the marketplace and the difficulties of making pathogen-free fresh products. Should FDA, in other words, purposefully permit competition between processed and unprocessed products, by letting both be labeled as "fresh," in order to achieve a secondary benefit — reduction in the risk of food-borne infection? With regard to fresh citrus juice, the answer provided by the NACMCF is clear. There is no need to compromise on the meaning of "fresh" for citrus juice. Indeed, the panel concluded that fresh citrus juice can be made pathogen-free without any post-extraction processing or treatment. Thus, planned food safety regulations will likely create a special niche for unpasteurized fresh citrus juice that has undergone no post-extraction treatment based on the recent recommendations of this panel.

Third, there are other existing food labeling regulations that apply to fresh citrus juice. There are currently three authorized health claims that are applicable to fresh fruits. In the case of citrus, in which the peel is not consumed, these regulations apply to claims that can be made about the fresh juice. 21 C.F.R. § 101.78(a)(2); *see also*, 21 C.F.R. § 101.76(a)(2) and §101.77(a)(3). The regulations make clear that the constituents of fresh fruit that impart these health benefits are unknown. Thus, the health claims cannot be made applicable to non-fresh fruit or citrus fruit juice that has been subjected to processing with unknown effects on the components of the juice that are responsible for the health effects.

In sum, the company believes that any regulations considered in this area should be cognizant of the special rules promulgated or proposed by FDA that are unique to fresh citrus juice — unprocessed after extraction.

The company's response, therefore, with regard to FDA's alternative proposals is clear — the unqualified term "fresh" for citrus juice applies to products that have undergone no post-extraction processing.

Taste v. organo-leptic characteristics

FDA has asked whether maintenance of organo-leptic characteristics could be substituted for lack of processing in the determination of whether a product is "fresh". A distinction must be made between organo-leptic testing and taste. Taste is entirely subjective, as scientific investigations into taste have shown, and varies from individual to individual. Organo-leptic testing can be objective but is not a measurement of taste.

To that end, organo-leptic testing is used to identify a specific odorificant and not the maintenance of the complex array of odorificants present in a fresh product. Currently, there are any number of organo-leptic tests applied to food. Individuals are trained to identify a characteristic odor of a specific chemical, such as trimethylamine or other chemicals, that are associated with degraded or rotten fish. Certain bitter flavors are present in improperly treated or harvested tea which can be detected and graded by professional tasters. The training of certain individuals in the detection of a specific known taste is an objective process that can be validated both by parallel chemical testing, especially when the odorificant is known, and by the lack of interobserver variability among trained individuals.

The same is not true of taste. The physiology of smell and taste make clear the difference. There are millions of chemical constituents in any organic product. Many are volatile; many are fat soluble. Of those, most will react with specific taste or olfactory sensors if the person both has the gene for the sensor and it is currently expressed. Taste is the complex combination of activation of multiple taste and olfactory sensors. The presence of sensors is determined both by genetics and expression. Thus, if there are 2 million possible sensors, any one individual may have genetic material for only a proportion of them and, at any one time, only a subset of these will be expressed. Thus, if a product has a thousand different odorificants, each person will detect only a percentage of those and this percentage will vary among individuals. Thus, the unique taste of a fresh product, while constant in one individual, is perceived by different people differently. The loss of a single odorificants may, therefore, effect one group of people but not another. There is, therefore, no one person or group of taste testers who can verify that there has been no change in odorificant content. The variation in type, concentration, and binding characteristics of olfactory and taste sensors are such that no two persons perceive the taste from the same organic product the same way. See Attachment at Tab 2 for a textbook example of the science underlying taste.

To that end, scientists have failed in their attempt to produce a catalogue of tastes. Henning tried to develop a "smell prism" by testing well over 400 different known odorous substances in multiple subjects. Unfortunately, the system doesn't work. It can't be validated in the next new subject because each person perceives some of the odors differently even among a small number such as 400. Other studies have shown clear and reproducible gender differences in the ability to

detect various odorificants. And, if that weren't complicated enough, expression of taste and olfactory sensors varies by time and age in the same individuals. See Tab 2.

In short, it is simply not technically feasible, nor will it ever be, given the physiology of taste, to identify that the taste of fresh citrus juice has not changed due to a processing of fresh citrus juice.

Quantifiable Other Parameters

FDA's other suggestion is that there may be chemically identifiable constituents of citrus juice that could be measured to determine if the product still retains "freshness" after some processing. The company must start with the predicate that an organic product contains millions of different chemical entities. Thus, it is simply not technically feasible to assure that there has been no change in any chemical constituent.

That should be the end of the search for a new meaning for "fresh" other than the one that has served us well until now. But, FDA may be suggesting that identity of known or already described nutrients before and after processing juice may serve as the test for a new meaning. This suggestion assumes that all important nutrients are well known and well-characterized and described, for instance, in 21 C.F.R. §101.9(c) or an authoritative textbook or compendium of nutrition.

Fresh orange juice is different, as noted above, and has different consumer values that relate to constituents beyond those identified as nutrients in § 101.9(c). During rule-making on the health claims applicable to fresh fruits and vegetables, FDA took notice of this difference. FDA noted that the specific components within fresh fruits and vegetables that were responsible for the health benefit could not be identified and put in a pill. As stated in one of these health claims, "the specific roles of the numerous potentially protective substances in plant foods are not yet fully understood." 21 C.F.R. § 101.78(a)(2); *see also*, 21 C.F.R. § 101.76(a)(2) and §101.77(a)(3). Time has passed since then, but the protein, enzymatic, and chemical components that produce the health benefits of fresh citrus are still a blank book. To that end, unlike other products, fresh citrus and its juice are the subject of three separate health claims covering reduction in risk from both cancer and heart disease. If the meaning of the word "fresh" is re-written to permit changes in content other than changes in specific known nutrients, these health claims would also have to be re-addressed and their applicability to processed juice re-assessed.

There are also well-characterized components, other than listed nutrients, of fresh citrus juice that have been postulated to provide specific benefits. Fresh citrus juice contains proteins and enzymes that are harmed by alternative microbial load reduction technologies. Many of these have been postulated to provide health benefits. In any event, the scientific data are in too early a phase of development to foreclose further research and investigation by taking a policy position that would eliminate the consumers' ability to identify and purchase fresh citrus juice that has undergone no post-extraction processing.

One example of this issue is that fresh citrus juice, like unpasteurized yogurt, contains *Lactobacillus sp. Lactobacillus sp.* are thought to elaborate agents which reduce and/or kill

common yeasts such as *Candida albicans*. Current medical therapy for persistent or refractory *Candida* infections includes treatment with foods that contain *Lactobacillus sp.* Post-extraction processing which would kill pathogens would also kill *Lactobacillus sp.* Finally, the ability of fresh citrus juice to maintain the benefits of a normal healthy human gut microflora, such as production of vitamin K, are unknown.

In sum, it is not possible in the case of fresh citrus juice to certify definitively that there are no changes in chemical constituents, because many of those constituents, which may be responsible for defined health benefits, are unknown.

Dictionary Definition

This may be the appropriate time to point out, as well, that the dictionary defines "fresh" as meaning "newly made" or "not preserved." In contrast, a product that is not "fresh" is one that spoils. A product which is microbe-free — having been sterilized of both potential pathogens as well as all other microbial life — does not spoil. Thus, The Fresh Juice Company believes that the consumer understands that a "fresh" product spoils and that the time to consumption is important for maintenance of the flavor and other potential benefits.

In sum, the company believes that consumers understand "fresh" to mean a citrus product that it is required to have freshness dating and which expires or changes unless quickly consumed.

Irradiation

The company also does not believe that post-extraction irradiated citrus juice should be permitted to be labeled as "fresh". There are other acceptable terms such as "cold pasteurized" that would be easily understood by the consumer, acceptable, and would permit differentiation by consumers of truly "fresh" citrus juice.

Additionally, as set forth in the IFT report, which is already referenced in the docket, irradiation produces changes in free radicals that will have some taste and content effects. Those effects are just different from the effects of thermal damage. Undesirable taste effects on other foods have also been reported from free radical generation.

Other Technologies

The company notes and re-emphasizes that the data supporting the effectiveness of alternative technologies without a change in taste and without a change in any chemical constituent are simply not currently available for any technology as set forth in the IFT report.

Conclusion

A citrus juice product that has been subjected to unnecessary post-extraction microbial load reduction in order to achieve pathogen reduction should never be entitled to use the unqualified term, "fresh," on its label. Such a product has been purposely processed to remove measurable components that are part and parcel of the product that The Fresh Juice Company's customers

want when they purchase fresh citrus juice, including beneficial microbes. And, since it is possible to achieve pathogen free citrus juice without post-extraction processing, there is no need to consider an alternative definition of "fresh" for citrus juice.

Responses to Specific Questions

1. Do consumers associate the term "fresh" with organo-leptic characteristics, nutritional characteristics, or some other characteristics?

   NO, the company's customers associate the unqualified term "fresh" in the context of fresh citrus juice with juice that has been unprocessed and untreated following extraction.

   Organo-leptic characteristics are useful for the objective identification of a specific volatile chemical. They are not useful for the identification of "no change" in a complex tasteful product. There is no "test" for taste.

   Nutritional composition is important especially if not limited to known nutrients, as set forth in published regulations governing health claims for juice products. Since it is not possible to identify changes in the many of components of citrus juice, use of nutritional characteristic stability is not a practicable method of identifying freshness.

2. Do consumers want a way to identify foods that taste and look fresh but have been processed to control pathogens?

   In the special case of citrus juice, this question is simply not necessary to ask, as it is possible to produce fresh citrus juice that tastes and looks fresh because it is fresh, without it being "processed to control pathogens" using post-extraction treatments. Additionally, consumers should not be confused by conflicting uses of the term "fresh" that would not permit consumers to identify which citrus products are subjected to no post-extraction processing.

3. What does industry think the term "fresh" means?

   In the context of citrus juice, the complete absence of any post-extraction processing or treatment results in fresh citrus juice.

4. Is the term "fresh" when applied to foods processed with the new technologies misleading to consumers?

   Yes. The term "fresh" when applied to citrus juice means the extracted juice is unprocessed. Such products do not have the taste or content for which the company's customers are looking — they are looking for unprocessed natural citrus juice.

5. Do the new technologies preserve the foods?

   The data in the IFT report indicates that many of the technologies have not been independently validated as effective preservatives.

6. Are the new technologies truly non-thermal?

   Most of the new technologies produce some thermal effects. Alternatively, the systems result in free radical generation. Either technology results in substantial alteration in the content of the product in known and unknown ways.

7. Are there quantifiable parameters, e.g., level of nutrients, vitamins, etc., that could be measured to determine if a food is "fresh?"

   There is no reliable assay to assure that citrus juice has not been changed when it is processed post-extraction by any method, because the level of microchemical contents cannot be assessed without a full catalogue of the contents. Citrus juice is a complex organic material with many minor components that are uncharacterized and that could have health and taste benefits.

8. Is there a term other than "fresh" that can be used for foods processed with the new technologies?

   The company believes that, for a fully independently validated process, the term "cold pasteurization" would provide a clear and simple way to distinguish from the other choices of thermal pasteurization, concentrate, and fresh citrus juice.

9. Would consumers understand a new term?

   U.S. consumers have shown themselves remarkably adaptable to new technologies, from cell phones to email, and to the new language that evolves around such new technology, from e-commerce to dot.coms. The company believes that FDA should require that new technologies used in food processing be described on the label by the manufacturer.

10. What is the economic impact of allowing use of the term "fresh" for foods processed with the new technologies?

    As stated at the meeting in Chicago, the company thinks the fresh citrus juice industry would be eliminated. Many of the firms involved in this business are small businesses. Based on existing authorized health claims, there are potential health benefits that would also be lost. It is difficult to calculate the economic impact of such a loss.

11. Would allowing the term "fresh" on foods processed with new technologies place small firms not able to use these technologies at an economic disadvantage?

Yes, as noted, for citrus juice, the company believes the result would be the elimination of thriving industry.

Sincerely,

Jur Strobos, M.D., J.D.

Cc:

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